II. Remarks

A. Status of the Claims

Claims 3-7 and 9-10 will be pending after entry of this amendment. Claims 1-2, 8 and 11-54 were previously cancelled. Claims 3, 4 and 7 have been amended without prejudice. Support for the amendments to claims 3, 4 and 7 can be found in the application as originally filed, specifically in original claims 9 and 10. Applicants respectfully submit that the amendments present no new matter and will not require a further search, as they are supported by originally filed claims 9 and 10.

B. Claim Rejections Under 35 U.S.C. §103(a)

In the Final Office Action, the rejection of claims 3-7, 9 and 10 was maintained under 35 U.S.C. §103(a) as being unpatentable over Reed et al. (WO98/16645).

Prior to addressing this rejection, Applicants wish to draw the Examiner's attention to claims 3, 4 and 7, which have been amended to include "at least one additional DNA sequence encoding a polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*". Further, Applicants point out that claims 9 and 10, as previously presented, also recite at least two DNA sequences, each encoding a polypeptide of the *Mycobacterium tuberculosis* complex that is not a polypeptide encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*.

With respect to the rejection over Reed et al., this rejection is respectfully traversed. Applicant submits that, in view of Reed et al., one of skill in the art would not be motivated to create a vector, cell, or composition, comprising a DNA molecule or sequence encoding MBTN4 polypeptide and at least one additional DNA sequence encoding a polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*, as recited in claims 3 and 4-7; or a composition comprising at least two DNA sequences, each encoding a polypeptide of the *Mycobacterium tuberculosis* complex that is not a polypeptide encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*, as recited in claims 9 and 10.

Applicants submit that, as acknowledged by the Examiner, Reed et al. do not teach or suggest vectors or host cells which incorporate SEQ ID NO:110, which is analogous to MTBN4.

Moreover, Applicants submit that Reed et al. do not teach or suggest vectors or host cells which incorporate SEQ ID NO:110 with at least one additional DNA sequence encoding a polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis.*

In further support of this position, Applicants respectfully direct the Examiner to Reed et al. at page 21, lines 24-27, which recites "[i]n embodiments in which more than one polypeptide is employed, the polypeptides used are preferably complementary (i.e., one component polypeptide will tend to detect infection in samples where the infection would not be detected by another component polypeptide)." Thus, the individual polypeptides combined in Reed et al. would have different characteristics in order to be complementary to each other. However, the polypeptides utilized in the polypeptide combination of the present claims share similar characteristics, i.e., each polypeptide is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis.* Therefore, in view of the teachings of Reed et al., Applicants submit that one of skill in the art would not be motivated to create a vector, cell, or composition, comprising a DNA molecule or sequence encoding MBTN4 polypeptide and at least one additional DNA sequence encoding a polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*, as recited in claims 3 and 4-7; or a composition comprising at least two DNA sequences, each encoding a polypeptide of the *Mycobacterium tuberculosis* complex that is not a polypeptide encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*, as recited in claims 9 and 10 of the present application.

Accordingly, Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973) 597-6162.

The undersigned also may be contacted via e-mail at epietrowski@lowenstein.com. All correspondence should be directed to the address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account 50-1358.

Respectfully submitted,
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